



MEDIA RELEASE

Ascend Biopharmaceuticals clinical trial program update

Highlights

- Clinical trial for skin cancer treatment to begin in H1, 2015
- Clinical trial for breast cancer to begin in H2, 2015

September 04, 2014: Ascend Biopharmaceuticals, a Melbourne-based immunotherapy company, has released an update on the clinical trial pipeline for its lead immunotherapy products treating basal cell carcinoma (BCC) and breast cancer.

The Company plans to begin a Phase 2 clinical trial on [ASN-002](#), an injectable immunotherapy for basal cell carcinoma (BCC), by H1 2015. Interim results from the trial are expected in mid-late 2015. Ascend has also announced plans to begin a Phase 1b study on a therapeutic cancer vaccine for breast cancer, [ASN-004](#), in the second half of 2015. Both trials are dependent on the completion of fundraising.

Skin cancer

BCC is a type of non-melanoma skin cancer, diagnosed in an estimated two million people every year. It is the most prevalent form of cancer in Australia, the US and Europe. Although surgery is the primary treatment for BCC, surgery is an undesirable option for many patients for clinical or cosmetic reasons.

ASN-002 is a product based on an adenovirus (a type of cold-virus) that has been engineered to produce a powerful anti-cancer protein called Interferon- γ . Ascend has secured an exclusive worldwide license to develop ASN-002 (formerly TG1042) from French biopharmaceutical company Transgene. Two clinical studies have already been completed in 51 patients with Lymphomas arising in the skin. These studies demonstrated that ASN-002 was safe, well tolerated and conferred highly favourable clinical responses.

“We are excited about evaluating ASN-002 in BCC patients. We believe this product has been de-risked by the previous clinical studies and there is a strong biological rationale for its use in BCC patients,” Ascend CEO Clement Leong said. “In addition, we believe that the previous clinical results provide support for the use of ASN-002 in treating a number of other cancers with important medical needs, including lymphomas of the skin, melanomas and bladder cancers”

Breast cancer

Ascend has also announced plans to begin a Phase 1b clinical study on its therapeutic cancer vaccine for breast cancer, **ASN-004**, in H2, 2015. Based on a product (OM-MUC-1) and platform originally developed at Melbourne’s Burnet Institute, ASN-004 is an injectable treatment that creates a powerful immune response directed at attacking breast cancers.



OM-MUC-1 has been studied in more than 10 clinical trials and in 100 patients. [A recent study](#) of OM-MUC-1 in 31 women showed it reduced the rate of breast cancer returning from 53 to six per cent at the 10-year mark.

Breast cancer is the most common cancer in Australian women, with around 14,000 new cases diagnosed every year. Metastatic breast cancer (MBC), where the cancer spreads from the original site, kills more than 425,000 people worldwide every year.

“At this time there are still a number of important clinical needs in breast cancer,” Dr Leong said.

“A significant percentage of early stage breast cancer patients will have their cancer return after primary treatments and metastatic breast cancer is currently incurable. ASN-004 has good potential to treat patients in these two breast cancer settings and we are looking forward to commencing further trials shortly.”

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About Ascend Biopharmaceuticals

Ascend is a clinical-stage company developing innovative cancer treatments. The company focuses on identifying disease settings where targeting the disease microenvironment or important cell types can bring about meaningful improvements in clinical outcomes.

Ascend has two clinical stage immunotherapy programs that have undergone previous clinical evaluation. The first product, ASN-002, will be assessed in basal cell carcinoma patients while the second product, ASN-004, is a pan-cancer therapeutic vaccine that will be studied in early stage breast cancer.

For more information, please visit www.ascendbiopharma.com or call +61 3 8606 3488.